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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,121	02/17/2004	Dipak K. Chowdhury		6473

7590 10/19/2005

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,121	CHOWDHURY ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Status of Claims

Claims 1-8 are currently pending and therefore examined herein on the merits for patentability.

Foreword Regarding Priority Date

Although the Applicants claim priority to: U.S. Non-provisional Patent Application Number 10/724,337; U.S. Provisional Patent Application Number 60/447,413; and U.S. Provisional Patent Application Number 60/447,414; the instantly claimed invention will only be given the benefit of the filing date of the instant application. More specifically, none of the aforementioned applications to which priority is claimed provide written description for a "buffer," a "water-soluble" excipient, a "detergent," a "sweetener," a "glidant," a "citrate" and "butylated hydroxytoluene" or "BHT." Therefore, the instantly claimed invention contains subject matter, which is not only broader in scope, but also not described in the aforementioned applications to which priority is claimed.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pre-Grant Patent Application Publication 2003/0021752 (hereinafter the Whittle '752 application).

Claims 1, 2, 5 and 7 of the instant application are directed to a pharmaceutical formulation for sublingual delivery of tetrahydrocannabinol in the form of a tablet, said pharmaceutical formulation

comprising: tetrahydrocannabinol; ethanol; a buffer; an antioxidant; a water-soluble excipient; a detergent; a sweetener; and a glidant. The buffer is selected from the group consisting of a citrate and a carbonate. The detergent is sodium lauryl sulfate. The glidant is magnesium stearate.

Similar to claims 1, 2, 5 and 7 of the instant application, the Whittle '752 application discloses a pharmaceutical formulation (abstract) for sublingual delivery of tetrahydrocannabinol in the form of a tablet ([0121]), said pharmaceutical formulation comprising: tetrahydrocannabinol ([0099]); ethanol ([0069]); a buffer ([100]); an antioxidant ([0051]; and [0073]); a water soluble excipient ([0066]; [0088]; [0147]; [0154]; and [0158]); a detergent (column 15, Table 2); a sweetener ([0088]; [0147]; [0154]; and [0158]); and a glidant ([0262]). More specifically, the buffer is a citrate buffer ([0100]; and column 15, Table 2). The detergent or emulsifier is sodium lauryl sulfate (column 15, Table 2). The glidant or lubricant is magnesium stearate ([0262]; [0263]; [0266]; and [0267]).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4 and 6 of the instant application are directed to a pharmaceutical formulation for sublingual delivery of tetrahydrocannabinol in the form of a tablet, said pharmaceutical formulation comprising: tetrahydrocannabinol; ethanol; a buffer; an antioxidant; a water-soluble excipient; a detergent; a sweetener; and a glidant. The antioxidant is butylated hydroxytoluene (BHT). The water-

soluble excipient is mannitol. The sweetener is saccharin. Claim 8 of the instant application is directed to a method of treating emesis, anorexia or wasting syndrome via the sublingual administration of said pharmaceutical formulation.

1. Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of the primary reference, namely the Whittle '752 application, in view of the secondary reference, namely U.S. Pre-Grant Patent Application Number 2002/0173549 (hereinafter the Wurtman '549 application).

With respect to claim 3 of the instant application, the Whittle '752 application teaches a pharmaceutical formulation comprising tetrahydrocannabinol and an antioxidant, wherein said antioxidant includes, but is not limited to, butylated hydroxyanisole (BHA), ascorbyl palmitate and α-tocopherol ([0051]; [0073]; and [0114]). On the other hand, the Whittle '752 application does not specifically mention utilizing BHT as the antioxidant. However, one of ordinary skill in the art would readily envision substituting butylated hydroxytoluene (BHT), which is another well-known antioxidant, in place of BHA. Notwithstanding the aforementioned, it would have been obvious to one of ordinary skill in the art to incorporate the BHT antioxidant taught by the Wurtman '549 application ([0074], as the antioxidant taught in the Whittle '752 application. Sufficient motivation, as well as a reasonable expectation of success, exists as the Wurtman '549 application teaches a pharmaceutical composition comprising a cannabinoid ([0037]) in combination with an antioxidant selected from the group consisting of: BHT; BHA; ascorbyl palmitate; and α-tocopherol ([0074]), while the Whittle '752 application likewise teaches a pharmaceutical composition comprising tetrahydrocannabinol incombination with an antioxidant selected from the group consisting of: BHA; ascorbyl palmitate; and α-tocopherol.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art reference.

2. Claims 4 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of the Whittle '752 application and U.S. Pre-Grant Patent Application Publication 2002/0035150 (hereinafter the Piomelli '150 application).

With respect to claim 4 of the instant application, the Whittle '752 application teaches a pharmaceutical formulation comprising tetrahydrocannabinol and a water-soluble excipient, wherein said water-soluble excipient is a sugar alcohol, such as glycerol, lactose, sorbitol and xylitol ([0066]; [0088]; [0147]; [0154]; and [0158]). On the other hand, the Whittle '752 application does not specifically mention utilizing mannitol as the water-soluble excipient. However, one of ordinary skill in the art would readily envision substituting mannitol, which is a sugar alcohol and a water-soluble excipient, in place of the sugar alcohols glycerol, lactose, sorbitol and xylitol. Notwithstanding the aforementioned, it would have been obvious to one of ordinary skill in the art to incorporate the mannitol water-soluble excipient taught by the Piomelli '150 application ([0128]; and [0137]), as the water-soluble excipient taught in the Whittle '752 application. Sufficient motivation, as well as a reasonable expectation of success, exists as the Piomelli '150 application teaches a pharmaceutical composition comprising a cannabinoid (abstract) in combination with a water-soluble excipient, such as lactose, sucrose, mannitol or sorbitol ([0128]), while the Whittle '752 application likewise teaches a

pharmaceutical formulation comprising tetrahydrocannabinol and a water-soluble excipient selected from the group consisting of glycerol, lactose, sorbitol and xylitol.

With respect to claim 6 of the instant application, the Whittle '752 application teaches a pharmaceutical formulation comprising tetrahydrocannabinol and a sweetener, wherein said sweetener is a sugar alcohol, such as glycerol, lactose, sorbitol and xylitol ([0066]; [0088]; [0147]; [0154]; and [0158]). On the other hand, the Whittle '752 application does not specifically mention utilizing saccharin as a sweetener. However, one of ordinary skill in the art would readily envision substituting saccharin, which is a well-known sweetener, in place of the sugar alcohols glycerol, lactose, sorbitol and xylitol. Notwithstanding the aforementioned, it would have been obvious to one of ordinary skill in the art to incorporate the saccharin sweetener taught by the Piomelli '150 application ([0130]; and [0131]), in place of the sugar alcohols taught in the Whittle '752 application. Sufficient motivation, as well as a reasonable expectation of success, exists as the Piomelli '150 application teaches a pharmaceutical composition comprising a cannabinoid (abstract) in combination with a sweetener, such as sucrose, glycerol, sorbitol, aspartame and saccharin ([0130]; and [0131]), while the Whittle '752 application likewise teaches a pharmaceutical formulation comprising tetrahydrocannabinol and a sweetener selected from the group consisting of glycerol, lactose, sorbitol and xylitol.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references.

3. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of the Whittle '752 application and U.S. Patent 5,804,592 (hereinafter the Volicer '592 patent).

With respect to claim 8 of the instant application, although the Whittle '752 application teaches a method of treating various conditions and disorders, as well as stimulating one's appetite ([0102]-[0109]; and column 7, Table 3), via the sublingual administration of a pharmaceutical formulation comprising tetrahydrocannabinol as the active ingredient (abstract; and [0121]), the Whittle '752 application does not specifically mention a method of treating emesis, anorexia or wasting syndrome. However, it would have been obvious to one of ordinary skill in the art to sublingually administer the tetrahydrocannabinol pharmaceutical composition taught by the Whittle '752 application (abstract; and [0121]) to treat emesis, anorexia or wasting syndrome, as the Volicer '592 patent teaches the sublingual administration of a pharmaceutical composition comprising dronabinol (a.k.a., Marinol®), which is a synthetic Δ^9-tetrahydrocannabinol, as the active ingredient to treat emesis (i.e., nausea and vomiting), anorexia and wasting syndrome (column 2, lines 5-11 and 39-46). Sufficient motivation, as well as a reasonable expectation of success, exists as the Volicer '592 teaches sublingually administering a pharmaceutical composition comprising a synthetic Δ^9-tetrahydrocannabinol for treating various pathological conditions, while the Whittle '752 application likewise teaches sublingually administering a pharmaceutical composition comprising naturally occurring tetrahydrocannabinol for treating various pathological conditions.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the

claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references.

Conclusion

Claims 1-8 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 7:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

JOHN PAK
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